EXHIBIT T

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Revised

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To: R. Rousseau

Re: Biocompatibility Risk Assessment for Soft PROLENE Mesh

The raw material used for the manufacture of Soft PROLENE mesh will the same material used for current PROLENE* polypropylene mesh as well as natural (uncolored) polypropylene suture. This mesh will have a new construction using smaller diameter (3.5 mil) polypropylene filaments with approximately 14% of the mesh weight contributed by filaments having the same composition as blue PROLENE polypropylene suture that is colored with up to 0.5% copper phthalocyanine blue pigment. The objective of this biocompatibility risk assessment was to determine the impact of this change on patient safety.

As indicated in the FDA G-95 Memorandum on the ISO 10993-1 guidelines entitled "Biological Evaluation of Medical Devices - Evaluation and Testing", the Soft PROLENE mesh device will be categorized as an implant device having permanent contact with tissue. As such, a number of biocompatibility tests including cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, subchronic toxicity, chronic toxicity, genotoxicity, implantation, and carcinogenicity need to be addressed. However, there is an extensive history of safe clinical use with polypropylene, specifically PROLENE mesh and natural and blue PROLENE suture, that demonstrates that this material is one of the most inert biomaterials available for implantation.

In accordance with the FDA guidance document entitled "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh", it is considered that the extensive clinical experience with these devices precludes the need to conduct cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, and subchronic toxicity studies. The chronic systemic toxicity and carcinogenicity of this material was evaluated using natural and blue PROLENE suture in the rat and dog indicating that this material was well-tolerated and non-carcinogenic (NDA 16-374; Vol. 1.1). This negative carcinogenicity result and long-term clinical experience preclude the need to conduct genotoxicity testing. A number of intramuscular and ophthalmic implantation studies have been conducted for natural and blue

*Trademark

PROLENE suture in the rat, dog, and rabbit for the original NDA as well as more recently where blue PROLENE suture was used as the control article in several studies (Intramuscular Tissue Reaction - PSE 97-0162, Ophthalmic Tissue Reaction - PSE 97-0218, and Dura Mater Tissue Reaction - PSE 98-0021). The results indicated that this "gold standard" material was well-tolerated and without adverse effects. In addition, an intramuscular tissue reaction study was conducted in rats where PROLENE mesh was used as the control article (PSE 97-0197). The results indicated that the tissue reaction was generally mild, and the presence of the mesh did not impair the healing response.

Since a major difference in the new Soft PROLENE mesh would be the presence of a portion of the filaments colored with up to 0.5% copper phthalocyanine blue pigment (approximately 14% of the mesh weight), the amount of pigmented mesh that the body would be exposed to was calculated. A worst-case exposure of two sheets of 12 x 12" sheets of mesh would equate to approximately 1.6 m of size 2-0 blue PROLENE suture. For Color Additive Petitions, it is generally accepted that safety needs to be assured for the amount of colorant in 10 m of size 2-0 suture to represent two major surgical procedures in a lifetime. Thus, the quantity of blue polypropylene that would be implanted in the body is well-below the amount that a long history of clinical use has demonstrated to be safe. In addition, copper phthalocyanine blue is considered to be an inert pigment commonly used to color polypropylene where it is bound within the polymeric material and is, therefore, unavailable to interact chemically with the body.

In summary, the preclinical study results and the extensive clinical experience with current PROLENE mesh, and natural and blue PROLENE suture demonstrate that this polypropylene base material, with or without copper phthalocyanine blue pigment, is intrinsically safe and without significant adverse effects for patients. It is considered that Soft PROLENE mesh manufactured with a portion of blue filaments will result in the same level of safety demonstrated by the currently marketed products, and no further preclinical testing is necessary.

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